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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-------------------------------|-------------|----------------------|---------------------|------------------|
| 10/723,908 | 11/26/2003 | Peter Andersen | 0459-0752P | 5514 |
| 2292 | 7590 | 02/20/2008 | | |
| BIRCH STEWART KOLASCH & BIRCH | | | EXAMINER | |
| PO BOX 747 | | | SWARTZ, RODNEY P | |
| FALLS CHURCH, VA 22040-0747 | | | ART UNIT | PAPER NUMBER |
| | | | 1645 | |
| | | | | |
| | | | NOTIFICATION DATE | DELIVERY MODE |
| | | | 02/20/2008 | ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

| | | | |
|------------------------------|-------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/723,908 | ANDERSEN ET AL. | |
| | Examiner | Art Unit | |
| | Rodney P. Swartz, Ph.D. | 1645 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 31 October 2007.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-12, 14-18 and 27-51 is/are pending in the application.
 - 4a) Of the above claim(s) 28-45 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-12, 14-18, 27 and 46-51 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) 1-12, 14-18 and 27-51 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicants' Response to Office Action, received 31 October 2007, is acknowledged. Claims 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 14, 17, 18, and 27 have been amended. Claims 13 and 19-26 have been canceled. New claims 46-51 have been added.
2. Claims 1-12, 14-18, and 27-51 are pending. Claims 28-45 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.
3. Claims 1-12, 14-18, 27, and 46-51 are under consideration.

Rejections Withdrawn/Moot

4. The rejection of claim 13 under 35 U.S.C. 101 because the claimed recitation of a use, is moot in light of the cancelation of the claim.
5. The rejection of claim 13 under 35 U.S.C. 112, second paragraph, as being indefinite for steps, is moot in light of the cancelation of the claim.
6. The rejection of claims 13 and 19-26 under 35 U.S.C. 112, second paragraph, as being indefinite for "immunologically equivalent" is moot in light of the cancelation of the claims.
7. The rejection of claims 13 and 19-26 under 35 U.S.C. 112, second paragraph, as being indefinite for what is being claimed, i.e., a fragment, or a whole polypeptide, is moot in light of the cancelation of the claims.
8. The rejection of claim 9 under 35 U.S.C. 112, second paragraph, as being indefinite for "derived" is withdrawn in light of the amendment of the claim.
9. The rejection of claim 10 under 35 U.S.C. 112, second paragraph, as being indefinite for "proline rich complex" and "19 kDa lipoprotein" is withdrawn in light of the amendment of the claim.

10. The rejection of claims 2-4 and 9 under 35 U.S.C. 112, second paragraph, as being indefinite for "as shown in" is withdrawn in light of the amendment of the claims.
11. The rejection of claim 19 under 35 U.S.C. 112, second paragraph, as being indefinite for "in the form of" is moot in light of the cancelation of the claim.
12. The rejection of claim 20 under 35 U.S.C. 112, second paragraph, as being indefinite for "in the form of" is moot in light of the cancelation of the claim.
13. The rejection of claim 27 under 35 U.S.C. 112, second paragraph, as being indefinite for "optionally in combination" is withdrawn in light of the amendment of the claim.
14. The rejection of claims 19, and 21-26 under 35 U.S.C. 112, first paragraph, scope of enablement for vaccines, is moot in light of the cancelation of the claims.
15. The rejection of claims 19 and 20 under 35 U.S.C. 102(e) as being anticipated by Alderson et al (U.S. Pat. No. 6,555,653, filed 5 May 1998) is moot in light of the cancelation of the claims.
16. The objection to Figure 1 is withdrawn in light of the amendment of the Brief Description.
17. The objection to Figure 2 is withdrawn in light of the amendment of the Brief Description.
18. The rejection of claims 1-12, 14-18, and 27 under 35 U.S.C. 112, second paragraph, as being indefinite for what is being claimed, i.e., a fragment, or a whole polypeptide, is withdrawn in light of the amendment of the claims.
19. The rejection of claims 16-18 under 35 U.S.C. 112, second paragraph, as being indefinite, is withdrawn.

20. The rejection of claims 1-7, 12, 14, and 27 under 35 U.S.C. 102(e) as being anticipated by Alderson et al (U.S. Pat. No. 6,555,653, filed 5 May 1998) is withdrawn in light of the amendment of the claims.

Rejections Maintained

21. The rejection of claims 1-12, 14-18, and 27 under 35 U.S.C. 112, second paragraph, as being indefinite for "immunologically equivalent" is maintained.

Applicants argue that page 13 of the specification clearly discloses that two or more polypeptides are immunologic equivalents when they both satisfy any one of the listed properties.

The examiner has considered applicants' argument, but does not find it persuasive. Page 13 states that "two polypeptide fragments are immunologically equivalent if they both satisfy property i), property ii), property iii), property iv), property v), property vi), property vii), or property viii)." Thus, the description is drawn to "fragment" equivalency, not to "polypeptides" as is presently claimed. Thus, it remains unclear what is meant by "immunologically equivalent" polypeptides.

Claim Rejections - 35 USC § 112

22. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

23. Newly added claims 46-51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Newly amended claim 1 now recites that the claimed polypeptide is "immunologically equivalent" to a polypeptide encoded by a member of the *esat-6* gene family. Page 13 of the

specification states that two polypeptide **fragments** are "immunologically equivalent" if they both satisfy property i, ii, iii, iv, v, vi, vii, or viii, wherein the properties are explained on pages 8-9. However, the specification does not define the term "immunologically equivalent" for whole polypeptides, and thus, the term is unclear.

Newly added claim 46-51 depend from claim 1, but do not clarify the issue.

24. Newly added claim 51 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claim is drawn to a composition comprising a polypeptide and a nucleic acid probe. Applicants indicate that support for the new claim is found in the specification on page 23, lines 5-14.

Page 23, lines 5-14, recite:

"In certain aspects, the DNA sequence information provided by this invention allows for the preparation of relatively short DNA (or RNA, PNA, or LNA) sequences having the ability to specifically hybridize to mycobacterial gene sequences. In these aspects, nucleic acid probes of an appropriate length are prepared based on a consideration of the relevant sequence. The ability of such nucleic acid probes to specifically hybridize to the 10 mycobacterial gene sequences lends them particular utility in a variety of embodiments. Most importantly, the probes can be used in a variety of diagnostic assays for detecting the presence of pathogenic organisms in a given sample. However, either use is envisioned, including the use of the sequence information for the preparation of mutant species primers, or primers for use in preparing other genetic constructs."

25. The recitation is drawn to only DNA sequences/probes and does not support the newly claimed combination composition of a polypeptide and nucleic acid. Likewise, the recitation in the specification of polypeptide compositions does not recite the combination composition of a

polypeptide and nucleic acid. Thus, claim 51 is considered new matter and therefore, was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Conclusion

26. No claims are allowed.
27. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).
Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

28. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Shannon Foley, can be reached on (571)272-0898.

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The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER
Art Unit 1645

February 1, 2008